

# Management's Discussion and Analysis

For the Three and Six Months Ended September 30, 2019

DATE OF REPORT: November 4, 2019

# MANAGEMENT'S DISCUSSION AND ANALYSIS

The following management's discussion and analysis ("MD&A") has been prepared as of November 4, 2019 and should be read in conjunction with the consolidated audited financial statements of Medicenna Therapeutics Corp. ("Medicenna", the "Company", "we", "our", "us" and similar expressions). The unaudited condensed consolidated interim financial statements and related notes of Medicenna, were prepared in accordance with International Financial Reporting Standards ("IFRS") and all dollar amounts are expressed in Canadian dollars unless otherwise noted.

# FORWARD-LOOKING STATEMENTS

This MD&A contains forward-looking statements within the meaning of applicable securities laws. These statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of the Company, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. All statements contained herein that are not clearly historical in nature are forward-looking, and the words such as "plan", "expect", "is expected", "budget", "scheduled", "estimate", "forecast", "contemplate", "intend", "anticipate", or "believe" or variations (including negative variations) of such words and phrases, or statements that certain actions, events or results "may", "could", "would", "might", "shall" or "will" be taken, occur or be achieved and similar expressions are generally intended to identify forward-looking statements. Forward-looking statements in this MD&A include, but are not limited to, statements with respect to the Company's:

- requirements for, and the ability to obtain, future funding on favorable terms or at all;
- business strategy;
- expected future loss and accumulated deficit levels;
- projected financial position and estimated cash burn rate;
- expectations about the timing of achieving milestones and the cost of the Company's development programs;
- observations and expectations regarding the effectiveness of MDNA55 and the potential benefits to patients;
- expectations about the Company's products' safety and efficacy;
- expectations regarding the Company's ability to arrange for the manufacturing of the Company's products and technologies;
- expectations regarding the progress, and the successful and timely completion, of the various stages of the regulatory approval process;
- expectations regarding the filing and approval of various submissions by regulatory agencies regarding the conduct of new clinical trials;
- ability to initiate, progress, and successful and timely completion, of various pre-clinical and manufacturing activities associated with future clinical trials;
- ability to secure strategic partnerships with larger pharmaceutical and biotechnology companies;
- strategy to acquire and develop new products and technologies and to enhance the safety and efficacy
  of existing products and technologies;
- plans to market, sell and distribute the Company's products and technologies;
- expectations regarding the acceptance of the Company's products and technologies by the market;
- ability to retain and access appropriate staff, management, and expert advisers;
- expectations with respect to existing and future corporate alliances and licensing transactions with third
  parties, and the receipt and timing of any payments to be made by the Company or to the Company in
  respect of such arrangements; and
- strategy with respect to the protection of the Company's intellectual property.

All forward-looking statements reflect the Company's beliefs and assumptions based on information available at the time the assumption was made. These forward-looking statements are not based on historical facts but rather

on management's expectations regarding future activities, results of operations, performance, future capital and other expenditures (including the amount, nature and sources of funding thereof), competitive advantages, business prospects and opportunities. By its nature, forward-looking information involves numerous assumptions, inherent risks and uncertainties, both general and specific, known and unknown, that contribute to the possibility that the predictions, forecasts, projections or other forward-looking statements will not occur. Factors which could cause future outcomes to differ materially from those set forth in the forward-looking statements include, but are not limited to:

- the effect of continuing operating losses on the Company's ability to obtain, on satisfactory terms, or at all, the capital required to maintain the Company as a going concern;
- the ability to obtain sufficient and suitable financing to support operations, preclinical development, clinical trials, and commercialization of products;
- the risks associated with the development of novel compounds at early stages of development in the Company's intellectual property portfolio;
- the risks of reliance on third-parties for the planning, conduct and monitoring of clinical trials and for the manufacture of drug product;
- the risks of reliance on third-parties for timely completion of on-going clinical trial activities, conduct of statistical analysis, imaging analysis, preparation of study reports and regulatory submissions;
- the risks associated with the development of the Company's product candidates including the demonstration of efficacy and safety;
- the risks related to clinical trials including potential delays, cost overruns and the failure to demonstrate efficacy and safety;
- the risks of delays and inability to complete clinical trials due to difficulties in securing ethics approvals and enrolling patients;
- risks associated with the Company's inability to successfully develop companion diagnostics for the Company's development candidates;
- risks associated with the Company's inability to successfully access drug delivery technology or materials and components required for drug delivery;
- risks associated with reliance on third parties for proper storage, packaging and shipment of active ingredients or other components required for pre-clinical or clinical trials;
- risks associated with product loss or degradation or failure of manufacturing batches and not meeting specifications for use in pre-clinical or clinical trials;
- delays or negative outcomes from the regulatory approval process;
- the Company's ability to successfully compete in the Company's targeted markets;
- the Company's ability to attract and retain key personnel, collaborators and advisors;
- risks relating to the increase in operating costs from expanding existing programs, acquisition of additional development programs and increased staff;
- risk of negative results of clinical trials or adverse safety events by the Company or others related to the Company's product candidates;
- the potential for product liability claims;
- the Company's ability to achieve the Company's forecasted milestones and timelines on schedule;
- financial risks related to the fluctuation of foreign currency rates and expenses denominated in foreign currencies;
- the Company's ability to adequately protect proprietary information and technology from competitors;
- risks related to changes in patent laws and their interpretations;
- the Company's ability to remain compliant with the terms of its agreement with the Cancer Prevention Research Institute of Texas ("CPRIT") and collect any remaining funding;
- the Company's ability to source and maintain licenses from third-party owners; and
- the risk of patent-related litigation and the ability to protect trade secrets.

Although the forward-looking statements contained in this MD&A are based upon what the Company's management believes to be reasonable assumptions, the Company cannot assure readers that actual results will be consistent with these forward-looking statements.

Any forward-looking statements represent the Company's estimates only as of the date of this MD&A and should not be relied upon as representing the Company's estimates as of any subsequent date. The Company undertakes no obligation to update any forward-looking statement or statements to reflect events or circumstances after the date on which such statement is made or to reflect the occurrence of unanticipated events, except as may be required by securities laws.

All references in this MD&A to "the Company", "Medicenna", "we", "us", or "our" refer to Medicenna Therapeutics Corp. and the subsidiaries through which it conducts its business, unless otherwise indicated.

# COMPANY OVERVIEW

Medicenna Therapeutics Corp. is the company resulting from a "three-cornered" amalgamation involving A2 Acquisition Corp ("A2"), 1102209 B.C. Ltd., a wholly-owned subsidiary of A2 and Medicenna Therapeutics Inc. ("MTI"), a privately held clinical stage biotechnology company. A2 was formed by articles of incorporation under the Business Corporations Act (Alberta) ("ABCA") on February 2, 2015, and following its initial public offering, was a "capital pool company" listed on the Toronto Stock Exchange Venture ("TSXV"). As a capital pool company, A2 had no assets other than cash and did not carry on any operations other than identifying and evaluating opportunities for the acquisition of an interest in assets or businesses for the completion of a qualifying transaction.

In February 2015, the Company received notice that it had been awarded a grant by CPRIT whereby the Company is eligible to receive up to US\$14,100,000 on eligible expenditures over a three year period (later extended to a five year period) related to the development of the Company's phase 2b clinical program for MDNA55.

On March 1, 2017, A2 completed its qualifying transaction in accordance with the policies of the TSXV by way of a reverse takeover of A2 by the shareholders of MTI (the "Qualifying Transaction"). In connection with the Qualifying Transaction, A2 changed its name to Medicenna Therapeutics Corp. and completed a consolidation of its share capital on the basis of one post-consolidation common share for every 14 pre-consolidation common shares (the "Consolidation").

On August 2, 2017, Medicenna graduated from the TSXV to the Toronto Stock Exchange ("TSX"). On November 13, 2017, Medicenna continued under the Canada Business Corporations Act.

Medicenna has three wholly owned subsidiaries: MTI, Medicenna Biopharma Inc. (Delaware) and Medicenna Biopharma Inc. (British Columbia).

Medicenna is a clinical stage immuno-oncology company developing novel, highly selective versions of IL-2, IL-4 and IL-13 tunable cytokines, called "Superkines". These Superkines can be developed either on their own as short or long-acting therapeutics or fused with cell killing proteins in order to generate Empowered Cytokines™ ("ECs") that precisely deliver potent toxins to the cancer cells without harming adjacent healthy cells. Medicenna's mission is to become the leader in the development and commercialization of targeted ECs and Superkines for the treatment of a broad range of cancers. The Company seeks to achieve its goals by drawing on its expertise, and that of world-class collaborators, in order to develop a unique set of therapeutic Superkines. Compared to naturally occurring cytokines – that bind to multiple receptor types on many cell types – Superkines are engineered with unique specificity toward defined target cell subsets to enable precise activation or inhibition of relevant immune cells in order to improve therapeutic efficacy and safety. Superkines can also be fused with other types of proteins such as antibodies to generate novel "immunocytokines" or combined with other treatment modalities such as checkpoint inhibitors, Chimeric Antigen Receptor T cells (CAR-Ts) or oncolytic viruses to stimulate tumor-killing immune cells or overcome the immunosuppressive tumor micro- environment. Medicenna completed enrolment in a Phase 2b clinical trial of MDNA55, Medicenna's lead EC, for the treatment of recurrent glioblastoma ("rGBM"), the most common and uniformly fatal form of brain cancer. MDNA55 is a fusion of a circularly permuted version of interleukin-4 ("IL-4"), fused to a potent fragment of the bacterial toxin, Pseudomonas exotoxin (PE), that is designed to preferentially target tumor cells that over-express the interleukin 4 receptor ("IL-4R"). MDNA55 has now been studied in 5 clinical trials in 132 patients, including 112 patients with rGBM, in which it has shown indications of superior efficacy when compared to the current standard of care. MDNA55 has secured Orphan Drug Status from the United States Food and Drug Administration ("FDA") and the European Medicines Agency as well as Fast Track Designation from the FDA for the treatment of rGBM and other types of high grade glioma. Medicenna announced on April 30, 2019 that patient enrollment was complete in the Phase 2b clinical trial of MDNA55 after treating 46 patients with rGBM. Medicenna announced preliminary top line data from the study on June 18, 2019. Medicenna plans to have an End of Phase 2 ("EOP2") meeting with the FDA and to have twelve month survival data on all patients in the study in early 2020.

Complementing Medicenna's lead clinical asset (MDNA55), the Company has built a deep pipeline of promising pre-clinical Superkine candidates such as IL-2 agonists ("MDNA109"), IL-2 antagonists ("MDNA209"), dual IL-4/IL-13 antagonists ("MDNA413") and IL-13 Superkine ("MDNA132") all in-licensed from Leland Stanford Junior University ("Stanford"). The most advanced of these programs is the MDNA109 platform, which is in pre-clinical development and is the only engineered IL-2 Superkine designed to specifically target CD122 (IL-2R $\beta$ ) with high affinity without CD25 dependency. The lead candidate from our IL-2 Superkine platform is MDNA19 (formerly known as MDNA109-LA1) which, unlike native IL-2 (Proleukin) has superior pharmacokinetic properties, lacks CD25 binding in order to improve safety, potently stimulates effector T cells, reverses Natural Killer (NK) cell anergy and acts with exceptional synergy when combined with checkpoint inhibitors.

# **ACHIEVEMENTS & HIGHLIGHTS**

The following are the achievements and highlights for the quarter ending September 30, 2019 through to the date hereof:

- On October 17, 2019, subsequent to the quarter-end, the Company completed a public offering raising total gross proceeds of \$6,900,000. The Company issued 5,307,693 units at \$1.30, consisting of one common share and one-half common share purchase warrant. Each whole warrant is exercisable at \$1.75 until October 17, 2022.
- On September 25, 2019, we presented updated efficacy results from the Phase 2b clinical trial (MDNA55-05) in the first 33 rGBM patients enrolled in the study. MDNA55 is a potent immunotherapy agent as it potently targets the IL-4R which is overexpressed in GBM as well as non-cancerous cells that make up the brain tumor microenvironment ("TME"). The data imply that targeting the TME, particularly in GBM, is critical where almost half of the tumor mass is made up of the TME - a cancer swamp that hides the tumor from the immune system. The TME is emerging as one of the key reasons why glioblastoma is extremely aggressive, and continues to be one of the most difficult cancers to treat. Since MDNA55 can simultaneously kill both the tumor cells and the TME by targeting the IL-4R, the results to date indicate that MDNA55 could emerge as a new treatment for this deadly disease.
- On September 30, 2019, we announced the presentation of new pre-clinical data from our IL-2 Superkine program to support the differentiating characteristics of long-acting MDNA109 variants and their potency *in vitro* and *in vivo* from other long-acting IL-2 programs.
- On September 26, 2019 Medicenna announced the publication of a peer-reviewed article in the August 2019 edition of *Nature Communications* providing independent third-party validation of Medicenna's IL-2 Superkine platform, MDNA109.
- On September 24, 2019, we announced the appointment of Ms. Karen Dawes to our Board of Directors. Ms. Dawes is an experienced and highly-regarded leader in the life sciences industry with extensive strategic expertise and considerable commercial background.

- On July 31, 2019, we announced the selection of MDNA19 (formerly, MDNA109-LA1) as our second immuno-oncology clinical candidate for the treatment of cancer. MDNA19 is a best-in-class long-acting IL-2 developed from Medicenna's Superkine platform that has shown unique ability to selectively stimulate cancer killing immune cells without the limitations seen with other long-acting IL-2 programs. Medicenna expects to file an IND for MDNA19 in late 2020.
- On July 9, 2019 Medicenna announced that it had received US\$1,915,372 (approximately, CD\$2.5M) in non-dilutive funding from CPRIT.

# FINANCING UPDATE

#### Three and six months ended September 30, 2019

On October 17, 2019, subsequent to the quarter-end, the Company completed a public offering raising total gross proceeds of \$6,900,000. The Company issued 5,307,693 units at \$1.30, consisting of 1 common share and ½ common share purchase warrant. Each whole warrant is exercisable at \$1.75 until October 17, 2022. The Company paid commission to the agents totaling \$455,174.99 and issued 350,134 warrants to the agents exercisable into one common share of the Company at an exercise price of \$1.30 for a period of twenty four months.

During the six months ended September 30, 2019, 224,655 warrants were exercised at a price of \$1.20 per share for proceeds of \$269,586.

No options or warrants were exercised in the three months ended September 30, 2019.

No options or warrants were exercised in the three and six month periods ended September 30, 2018.

#### **RESEARCH & DEVELOPMENT UPDATE**

#### MDNA55

Excluding the recently completed Phase 2b clinical study, MDNA55 has been studied in previous clinical trials under two Investigational New Drug Applications ("IND") for the treatment of rGBM, high grade glioma and non-CNS solid tumors. In these earlier studies, MDNA55 showed promising clinical results from 72 patients including 66 adult patients with rGBM following a single intra-tumoral infusion. It has secured Orphan Drug Status from the FDA and the EMA as well as Fast Track Designation from the FDA.

Since the above mentioned clinical trials, there have been many improvements to the convection enhanced delivery ("CED") technology, a drug delivery technique for localized administration of MDNA55 into brain tumors. This includes use of newly developed techniques for high precision placement of catheters into the tumor bed as well as novel stepped design catheters that prevent backflow and leakage of MDNA55 during treatment. Furthermore, by co-infusion of a magnetic resonance imaging ("MRI") contrast agent with MDNA55, drug distribution can be monitored in real-time in order to achieve maximum coverage of the tumor bed and the tumor margins. Unlike previous clinical trials, early data from the MDNA55 Phase 2b clinical trial presented in October and November 2017, show that each of these improvements facilitates more accurate targeting and superior distribution of MDNA55 to regions of active tumor growth as well as the margins around the tumor. Medicenna has obtained an exclusive license from the National Institute of Health ("NIH") to patents covering CED and the use of a surrogate tracer for real-time monitoring of MDNA55 delivery and distribution.

#### Phase 2b Study Outline for Glioblastoma at First or Second Recurrence or Progression

The Phase 2b trial with MDNA55 using enhanced CED delivery is a multi-center, open-label, single-arm study in up to 52 patients (at least 46 patients evaluable for survival and 35 patients evaluable for response), with first or second recurrence or progression of GBM after surgery or radiotherapy ± adjuvant therapy or other experimental therapies.

The primary endpoint of the study is median Overall Survival (mOS) comparing a null survival rate of 8.0 months (based on historical control) with an alternative pursue rate of 11.5 months (1-sided alpha = 0.10 and 80% power for 46 ITT or Per Protocol subjects). The secondary endpoint is objective response rate (ORR) assessed by the modified Response Assessment in Neuro-Oncology (mRANO)-based criteria incorporating advanced imaging modalities according to a null response rate of 6% with an alternative pursue rate of 18% (1-sided alpha = 0.10 and 80% power for at least 35 subjects evaluable for response). IL4R expression levels in tumor biopsies and their potential impact on patient outcomes following treatment with MDNA55, were and are being retrospectively evaluated.

#### Phase 2b Study Update

In April 2017, we treated the first rGBM patient in the Phase 2b clinical trial of MDNA55 and enrolled patients at eight clinical sites across the United States and Europe with enrolment in the study (46 ITT patients) completed in April 2019.

While the Company previously targeted completion of the Phase 2b by not later than Q4 2018, the protocol amendments announced in September 2017 and May 2018, and described below, resulted in slower than anticipated patient recruitment.

On September 28, 2017 we announced that based on encouraging drug distribution and safety data observed we implemented an amended protocol incorporating enhanced drug delivery procedure which was used for the treatment of the remaining patients. The amended protocol allowed higher doses and volumes of MDNA55 as well as an increase in the total expected study size – from 43 patients under the original protocol to up to 52 total planned patients. This protocol amendment was based on a planned safety analysis following a unanimous recommendation from MDNA55's Safety Review Committee. Of the up to 52 patients to be treated in the study we required at least 46 of those patients to be evaluable for survival and at least 35 subjects evaluable for response. We met our threshold enrolment requirements in April 2019 with 46 patients treated.

On October 10, 2017, clinical data was presented by Principal investigator John H. Sampson MD, PhD, (Robert H. and Gloria Wilkins Distinguished Professor and Chair of Neurosurgery at Duke University in Durham, NC) at the 2017 Congress of Neurological Surgeons (Boston, MA), demonstrating successful delivery of MDNA55 in rGBM patients and a reassuring safety profile. Furthermore, the data showed that a substantially higher proportion of the target tissue was being covered then in previous similar trials. In some cases, close to 100% of the tumor and the 1cm margin around it (at risk for tumor spread) had been successfully covered.

Additional clinical data from the Phase 2b rGBM clinical trial of MDNA55 were presented at the 22nd Annual Meeting of the Society of Neuro-Oncology ("SNO") held in San Francisco in November 2017. Dr. Krystof Bankiewicz, MD, PhD, Professor in Residence of Neurological Surgery at the University of California San Francisco, provided an update on drug distribution and safety data from the first 15 patients treated in the study. The oral and poster presentations at the SNO conference outlined that through a process of real-time image guided delivery together with the ability to monitor and adjust infusion parameters, drug delivery was dramatically improved with significant enhancement in target coverage. A previous CED study in rGBM, without the advances implemented by Medicenna, [ref: J Neurosurg. 2010 Aug;113(2):301-9], was able to achieve, on average, coverage of only 20% of the target volume. In contrast, in the current study, a comparable estimate for coverage of the tumor and a 1cm high-risk margin around it showed approximately 65% coverage with the figure rising to 75% for the tumor area alone, with some patients achieving near 100% coverage of the target volume.

It was reported on May 2, 2018 that half the patients in the study had been recruited and the data to date demonstrated solid safety results and early signals of efficacy based on the findings of the Safety Review and Clinical Advisory Committees, comprised of key opinion leaders and study investigators. Following the Safety Review, Medicenna amended the protocol at the recommendation of clinical advisors to further improve the chances for demonstrating increased therapeutic benefit for patients. The amendment allowed the implementation of optimal methodologies including more personalized dosing based on the tumor load, incorporation of advanced imaging modalities to measure treatment responses more reliably, use of sub-

therapeutics dose of Avastin in patients that could not tolerate steroid use to control edema and inflammation and allowing investigators to administer a second dose of MDNA55 where appropriate.

Review of some patients who had been withdrawn from the study, believing that their disease had progressed, found that the apparent increases in tumor volumes, seen on brain scans, were, in fact, due to tissue necrosis, inflammation and edema. This is a known effect of immunotherapeutic agents such as MDNA55, called pseudoprogression, which poses a challenge to patient retention, management and data interpretation. When evaluating images from such patients, using multi-modal imaging, Medicenna found evidence of biological activity of MDNA55 suggesting that these patients were benefiting from the treatment, and in multiple cases following withdrawal from the study, surgical resection showed significant tumor necrosis. This amendment allowed a biopsy and/or advanced multi-modal imaging to more accurately discriminate between necrosis/inflammation and true disease progression. These tools would encourage subjects to remain in the study, where appropriate, giving time for the pseudo-progression to resolve and increase the likelihood of clinical responses.

Following the amended protocol as announced on May 2, 2018 and after receiving the necessary regulatory and site approvals patient enrolment was resumed at higher doses provided that the pre-established maximum tolerated dose ("MTD") of 240µg was not to be exceeded.

The protocol amendments announced September 28, 2017 and May 2, 2018 resulted in increased timelines for completion of the MDNA55 Phase 2b clinical trial due to an increase in the original number of patients as well as slow down of patient recruitment while the necessary regulatory reviews and approvals were completed.

On October 22, 2018, the Company presented results and participated in a poster discussion session at the ESMO Congress held in Munich. Based on interim data from patients treated at low doses implemented during the first half of the Phase 2b study of MDNA55, the presentation highlighted the benefits of using of advanced imaging modalities in order to help tumor response evaluation and identify pseudo-progression in some patients which ultimately translates into tumor shrinkage, and potential treatment benefit.

On October 31, 2018, Medicenna provided an interim update from the ongoing Phase 2b clinical trial of MDNA55 for the treatment of rGBM. These results were superseded by data reported on February 7, 2019 as described below.

On February 7, 2019 Medicenna presented new clinical study results in a podium presentation entitled, "The IL4 Receptor as a Biomarker and Immunotherapeutic Target for Glioblastoma: Preliminary Evidence with MDNA55, a Locally Administered IL-4 Guided Toxin" by John H. Sampson, MD, PhD, Robert H. and Gloria Wilkins Distinguished Professor and Chair of Neurosurgery at Duke University during the 5<sup>th</sup> Annual Immuno-Oncology 360° Conference held in New York, NY. Following treatment with MDNA55 at the low dose, the IL4R positive group showed a remarkable increase in mOS of 15.2 months when compared to 8.5 months in the IL4R negative group. Survival rates at 6, 9, and 12 months were 100%, 67% and 55% versus 73%, 40%, and 30%, in the IL4R positive and negative groups, respectively. In addition, Dr. Sampson presented that irrespective of IL4R expression, mOS was 11.8 months in all patients following a single treatment with MDNA55 at the low dose with an overall survival rate of 89% at 6 months, 59% at 9 months and 46% at 12 months, substantially exceeding landmark mOS and survival rates reported for approved drugs for rGBM (mOS is 8 months for Avastin and Lomustine and survival rates at 6, 9 and 12 months are 62%, 38%, 26% and 65%, 43%, 30%, respectively). In these participants, patients with IL4R positive tumors showed a faster time to relapse (10.3 months) following initial diagnosis of GBM when compared to patients with low to no expression of IL4R (16.7 months) supporting published research showing that the Type 2 IL4R is a key biomarker for more aggressive forms of GBM.

On April 30, 2019 we announced that enrolment in the study was complete with 46 evaluable patients.

On June 3, 2019 a poster entitled "MDNA55: A Locally Administered IL4 Guided Toxin as a Targeted Treatment for Recurrent Glioblastoma" was presented at the 55th Annual Meeting of the American Society of Clinical Oncology (ASCO) held in Chicago, IL. The presentation by Dr. Dina Randazzo of Duke University School of Medicine and a Principal Investigator, focused on the development of a new biomarker test for the interleukin-4

receptor (IL4R) that may enable better selection and superior treatment outcomes for patients with rGBM. This data was subsequently updated at the World Pharma Conference described below.

On June 18, 2019, Dr. Fahar Merchant presented results from the Phase 2b MDNA55 clinical trial which recently completed enrollment (N=46) at the Inaugural Immuno-Oncology Pharma Congress in Boston, MA. The presentation highlighted disease control in up to 83% of the patients according to iRANO criteria (immunotherapy Response Assessment in Neuro-Oncology) which measures tumor response relative to the largest tumor size post-treatment (nadir). Use of advanced imaging techniques (such as perfusion and diffusion MRI) was able to show underlying tissue response amidst inflammation and edema in some subjects. In addition, safety data from the Phase 2b clinical trial show a similar safety profile to previous MDNA55 trials, with no systemic toxicities, no clinically significant laboratory abnormalities and no drug-related deaths.

On September 25, 2019, we presented updated efficacy results from the Phase 2b clinical trial MDNA55-05 in rGBM patients using the IL-4R as an immunotherapy target, as it is overexpressed in glioblastoma as well as in cells that make up the brain tumor microenvironment ("**TME**"). The data imply that targeting the TME, particularly in GBM, is critical where almost half of the tumor mass consists of non-cancerous cells that make up the TME - a cancer swamp that hides the tumor from the immune system. The TME is emerging as one of the key reasons why glioblastoma is extremely aggressive, and continues to be one of the most difficult cancers to treat. Since MDNA55 can simultaneously kill both the tumor cells and the TME by targeting the IL-4R, the results to date continue to show that MDNA55 is likely to emerge as a new treatment for this deadly disease.

Highlights from the presentation are summarized below:

- Irrespective of IL-4R status, mOS in subjects treated at low doses of MDNA55 (n=21) is 11.8 months; this is sustained when high dose subjects with mature survival data are added (n=33 total; mOS 11.9 months). However in the first 12 of 25 patients receiving the high dose, mOS is 16.7 months. This substantially exceeds landmark mOS reported for approved drugs for rGBM (mOS is 8-9 months for Avastin and Lomustine).
- Following treatment with MDNA55 at low doses (median 63µg; n=21), mOS of subjects with high IL-4 receptor expression (IL-4R<sup>High</sup>; n=12), a biomarker for aggressive disease, is 13.7 months compared to 8.1 months in subjects expressing no/low IL4R (IL-4R<sup>Low</sup>; n=8).
- When updated to include survival data from subjects treated at higher doses (median 180µg; n=12), MDNA55 continues to show promising survival outcomes in subjects with high IL-4R expression: mOS in the IL-4R<sup>High</sup> group (n=19) is 15.2 months as compared to 8.5 months in the IL-4R<sup>Low</sup> group (n=11).
- In the 33 subjects, irrespective of IL4R expression, subjects showing tumor shrinkage or stabilization from nadir (tumor control rate of 81%; 25 of 31 evaluable subjects) were seen to live longer than those with progressive disease (mOS of 16.1 months versus 8.3 months, respectively). These results are consistent with earlier reports suggesting that occurrence of immunogenic cell death following treatment with MDNA55 is associated with improved clinical prognosis and survival.
- Furthermore, safety data in the 12 additional subjects treated at higher doses of MDNA55 (median total dose 180µg) show a similar safety profile to previous MDNA55 trials with no systemic toxicities or drug related deaths.

Results for the majority of remaining patients participating in the Phase 2b clinical trial MDNA55-05 will be released before the end of 2019 followed by the EOP2 meeting with the FDA in Q1 2020.

The Company expects the completion of clinical development of MDNA55 to full approval (including a pivotal Phase 3 clinical trial), if undertaken by Medicenna, to last until at least 2021, with a projected aggregate cost of up to approximately \$75 million, incremental to the current cash on hand. It is anticipated that following the successful completion of the Phase 2b clinical trial and a successful EOP2 meeting with the FDA the Company will work to out-license the program to one or more partners who would fund or co-fund Phase 3 clinical

development of MDNA55 as well as prepare the program for commercialization and its subsequent launch in various countries where approval has been granted. In addition to development and regulatory approval of MDNA55, the Company and/or its partner may also have to develop and commercialize a companion diagnostic to test for IL4R expression prior to treatment with MDNA55. See "Risk Factors" below.

#### Superkine and Empowered Cytokine Platforms

#### **IL-2** Superkines

IL-2 was one of the first effective immunotherapies developed to treat cancer due to its proficiency at expanding T cells, the central players in cell-mediated immunity. Originally discovered as a growth factor for T cells, IL-2 can also drive the generation of activated immune cells, immune memory cells, and immune tolerance.

In contrast, IL-2 induced overstimulation of immune cells can lead to an imbalance in the ratio of effector and regulatory T cells, resulting in autoimmune diseases.

Part of the reason for this is due to the nature of the IL-2 receptor.

The IL-2 receptor is composed of three different subunits, IL-2R $\alpha$  (also known as CD25), IL-2R $\beta$  (CD122) and IL-2R $\gamma$  (CD132). The arrangement of these different proteins determines the response to IL-2 signaling.

The IL-2 $\beta$  and IL-2 $\gamma$  components together make a receptor capable of binding IL-2, but only moderately so. When all three components are together, including IL-2R $\alpha$ , the receptor binds IL-2 with a much higher affinity. This complete receptor is usually found on regulatory T cells (Tregs), which dampen an ongoing immune response. The lower affinity receptor, composed of just the IL-2 $\beta$  and IL-2 $\gamma$  components, is more often found on "naive" immune cells, which are awaiting instructions before seeking out cancer cells.

Altering IL-2's propensity for binding these receptors could encourage greater immune cell activation or block the function of regulatory cells.

Medicenna's MDNA109 (a precursor for our lead candidate, MDNA19) and MDNA209 take advantage of this dynamic by binding to specific receptors and either activating or blocking them.

MDNA109 (a precursor for our lead candidate, MDNA19) is an enhanced version of IL-2 that binds up to 200 times more effectively to IL-2R $\beta$ , thus greatly increasing its ability to activate and proliferate the immune cells needed to fight cancer. Because it preferentially binds IL-2R $\beta$  and not the receptor containing IL-2R $\alpha$ , MDNA109 drives effector T cell responses over regulatory T cells. Additionally, MDNA109 reverses Natural Killer (NK) cell anergy and acts with exceptional synergy when combined with checkpoint inhibitors.

On August 2, 2018, we announced preliminary pre-clinical data on MDNA109 (a precursor for our lead candidate, MDNA19), the only IL-2 in development with high affinity to CD122 to boost cancer fighting T cells, showing that fusions of MDNA109 with inactive protein scaffolds are long-acting and provide the convenience of easier dosing without sacrificing its safety and efficacy.

On February 6, 2019 the Company presented new results on MDNA109 (a precursor for our lead candidate, MDNA19) and its long acting variants in a podium presentation entitled, "Putting Pedal to the Metal: Combining IL-2 Superkine (MDNA19) with Checkpoint Inhibitors" by Moutih Rafei, PhD, Associate Professor, Department of Pharmacology and Physiology, Université de Montreal at the 5th Annual Immuno-Oncology 360° Meeting in New York, NY.

The results presented demonstrated that MDNA109 (a precursor for our lead candidate, MDNA19) exhibited 200-fold enhanced affinity toward the CD122 receptor and best-in-class potency toward cancer killing effector T cells. When tested in vivo, MDNA109 was not immunogenic and led to potent delay in the growth of preestablished B16F10 melanoma tumors compared to IL-2. Likewise, significant delay in the growth of preestablished MC38 and CT-26 colon cancer was observed in syngeneic mice receiving MDNA109, whereas its co-administration with anti-PD1 checkpoint inhibitor eliminated tumors in 90% of MC38 tumor-bearing mice. Furthermore, MDNA109 in combination with anti-CTLA-4 antibody, complete responses were observed in a majority of mice in the CT26 model. When cured animals were re-challenged on the counter-lateral flank with CT26 tumor cells, tumor growth was blocked at the secondary site clearly suggesting the generation of potent memory responses. Additional results on long-acting MDNA109 variants with impaired CD25 binding demonstrated abrogation of regulatory T cell activation at therapeutic doses in order to mitigate peripheral side effects, which are dependent on CD25 binding.

Medicenna presented a poster entitled "Engineering a long-acting CD122 biased IL-2 superkine displaying potent anti-tumoral responses" at the Inaugural Immuno-Oncology Pharma Congress, held from June 18-20, 2019 during World Pharma Week in Boston, MA. Highlights from the presentation by Dr. Moutih Rafei included the following: A) When MDNA109-LA (a precursor for our lead candidate, MDNA19) was co-administered with the immune-checkpoint blocker anti-cytotoxic T-Lymphocyte-Associated Protein (CTLA)4 in a colon cancer mouse model, 67% of animals with pre-established tumors remained tumor-free for over 100 days. When these animals received a second and third re-challenge of the tumor without further treatment, 100% and 75% remained tumor free, respectively, demonstrating a strong memory response. B) A long-acting variant, MDNA109-LA1 (aka MDNA19), engineered to mitigate Treg activation by abolishing binding to the CD25 had 50-fold decreased Treg activity and 6-fold higher activity towards naïve CD8 T cells for an overall 300-fold preferential activation of cancer killing T cells than recombinant IL-2. C) In addition, binding affinity studies using surface plasmon resonance confirmed absence of CD25 binding by MDNA109-LA1. D) To further validate the potency of MDNA109-LA1 mice with pre-established aggressive B16F10 melanoma tumors showed potent tumor control with a weekly dosing schedule.

On July 31, 2019, we announced the selection of MDNA19 (formerly, MDNA109-LA1) as our second immunooncology clinical candidate for the treatment of cancer. MDNA19 is a best-in-class long-acting IL-2 developed from Medicenna's Superkine platform that has shown unique ability to selectively stimulate cancer killing immune cells without the limitations seen with other long-acting IL-2 programs. We expect to begin clinical trials with MDNA19 in 2020.

On September 26, 2019, we announced the publication of a peer-reviewed article in the August 2019 edition of *Nature Communications* providing independent third-party validation of Medicenna's IL-2 Superkine platform, MDNA109.

The publication titled "A next-generation tumor-targeting IL-2 preferentially promotes tumor infiltrating CD8+ Tcell response and effective tumor control" describes the safety, efficacy, pharmacokinetics, immunogenicity as well as efficacy profile in different tumor models of long-acting variants of MDNA109 including fusions to antibodies to create tumor targeted immunocytokines.

The work reported in the publication is covered by our patents and patents in-licensed by us.

On September 30, 2019, we announced the presentation of new pre-clinical data from our IL-2 Superkine program. The presentation by Dr. Minh To, Director of Pre-clinical development at Medicenna, reported additional preclinical data to support the differentiating characteristics of long-acting MDNA109 variants and their potency in vitro and in vivo from other long-acting IL-2 programs.

Highlights from the presentation are summarized below:

- High potency towards naïve effector T cells but diminished potency on unwanted regulatory T cells (Tregs).
   Of the long-acting MDNA109 variants, MDNA19 is superior in having decreased binding to CD25 and increased affinity to CD122, therefore selectively activating cancer killing CD8 T cells instead of tumor protecting Tregs.
- Potent effects as monotherapy with improved PK characteristics. In CT26 (mouse colon cancer) and B16F10 (mouse melanoma) models, treatment with long acting variants of MDNA109 (biweekly for 2 weeks or once

weekly for 2 or 3 weeks) potently inhibited tumor growth. These data suggest that long-acting MDN109 variants could lead to potent therapeutic effects with a dosing schedule similar to that used for immune checkpoint inhibitors (CPI). In addition, the results also confirm that different protein scaffolds may be used to extend the half life of MDNA109 and can provide similar tumor control as MDNA19.

- Compelling preclinical synergism with immune checkpoint inhibition. In a pre-established colon cancer CT26 model, long-acting MDNA109 variants co-administered with the immune-checkpoint blocker anti-cytotoxic T-Lymphocyte-Associated Protein (CTLA)4, showed significant tumor growth inhibition with as many as 89% of animals remaining tumor-free for over 175 days.
- Strong Memory Response. Furthermore, tumor free animals receiving a second and third re-challenge of the tumor without further treatment remained tumor free in up to 100% of mice, demonstrating development of a strong memory response with the ability to prevent tumor relapses.

MDNA209 can be used to induce the opposite effect. This Superkine mimics the shape of IL-2 and also binds 500 to 1,000 times effectively to IL-2R $\beta$ . But rather than triggering IL-2 signaling, MDNA209 acts as an antagonist, blocking the receptor and preventing it from transmitting the signal. This could be used for diseases such as autoimmune disorders where it is essential to prevent T cells from becoming activated and attacking healthy tissue. Development timelines for MDNA209 have yet to be established.

As preparing, submitting, and advancing applications for regulatory approval, developing products and processes and clinical trials are sometimes complex, costly, and time consuming processes, an estimate of the future costs related to the development of MDNA19 and MDNA209 is not reasonable at this time.

## IL-4 and IL-13 Superkines

Medicenna's IL-4 and IL-13 Superkines are engineered versions of wild type cytokines which possess enhanced affinity and selectivity for either the Type 1 or Type 2 IL4R. This selectivity is achieved through mutations of the IL-4 or IL-13 proteins to enhance affinity for binding to specific IL4R subunits. Additional mutations have also been engineered to modulate their bioactivity, resulting in Superkines with enhanced signaling (super-agonists) or the ability to block signaling (super-antagonists).

One promising IL-13 Superkine antagonist is MDNA413. Compared to wild type IL-13, MDNA413 has been engineered to have 2,000-fold higher selectivity for the Type 2 IL4R and which potently blocks IL-4 and IL-13 signaling (Moraga et al, 2015). Blocking of Type 2 IL4R by MDNA413 may be relevant not only for targeting solid tumors that overexpress this receptor, but also for Th2-mediated diseases such as atopic dermatitis, asthma and idiopathic pulmonary fibrosis. With commercial validation of the IL-4/IL-13 axis as an effective therapeutic target for atopic dermatitis and asthma, Medicenna believes a topical or aerosol formulation of MDNA413 may be an important differentiated product compared to a blocking antibody (Dupixent®: Regeneron Pharmaceuticals and Sanofi) approved by the FDA for the treatment of moderate to severe atopic dermatitis. Dupixent® is administered by subcutaneous injection every other week. Development timelines for MDNA413 have yet to be established.

Another promising IL-13 Superkine is MDNA132. Unlike MDNA413, MDNA132 is an IL-13 ligand that has been engineered to increase affinity for IL13R alpha2 overexpressed on certain solid tumors while exhibiting sharply decreased affinity for IL13R alpha1. Medicenna believes MDNA132 has superior targeting compared to other IL-13 variants in development, and is an attractively differentiated targeting domain for inclusion in new and exciting field of immuno-oncology based on the CAR-T platform. Development timelines for MDNA132 have yet to be established.

As preparing, submitting, and advancing applications for regulatory approval, developing products and processes and clinical trials are sometimes complex, costly, and time consuming processes, an estimate of the future costs related to the development of MDNA413 and MDNA132 is not reasonable at this time.

### SELECTED FINANCIAL INFORMATION

	Six months Septemb		Three months ended September 30, 2019		
	2019	2018	2019	2018	
	\$	\$	\$	\$	
General and Administration	1,104,087	857,914	642,548	443,363	
Research and Development	2,074,734	1,080,787	1,246,292	445,814	
Net Loss	(3,198,893)	(1,935,876)	(1,904,259)	(897,659)	
Basic and Diluted Loss per Share	(0.11)	(0.08)	(0.07)	(0.04)	
Total Assets	2,243,789	3,408,806	2,243,789	3,408,806	
Total Liabilities	2,050,249	2,173,528	2,050,249	2,173,528	

We have not earned revenue in any of the previous fiscal years, other than income from interest earned on our cash balances.

For the six months ended September 30, 2019, we reported a net loss of \$3,198,893 or \$0.11 per share compared to a loss of \$1,935,876 or \$0.08 per share for the six months ended September 30, 2018. For the three months ended September 30, 2019, we reported a net loss of \$1,904,259 or \$0.07 per share compared to a loss of \$897,659 or \$0.04 per share for the three months ended September 30, 2018. The increase in net loss for the three and six months ended September 30, 2019 compared with the three and six months ended September 30, 2018 was primarily a result of a lower amount of costs reimbursed under the CPRIT grant.

We utilized cash in operating activities of \$4,198,703 in the six months ended September 30, 2019 compared with \$3,937,684 in the six months ended September 30, 2018. The increase in cash utilized in the current six month period is primarily the result of a reduction in accounts payable and accrued liabilities balances.

#### **RESULTS OF OPERATIONS FOR THE THREE AND SIX MONTHS ENDING SEPTEMBER 30, 2019**

#### Research and Development Expenses

	Six months ended September 30,		Three mon	
<u></u>	2019	2018	Septem 2019	2018
	\$	\$	\$	\$
Chemistry, manufacturing and controls	125,170	137,218	37,719	59,550
Regulatory	131,241	12,089	83,105	4,616
Discovery and pre-clinical	822,064	445,609	327,644	117,621
Research & Development Warrant	-	473,716	-	236,858
Clinical	834,843	1,671,526	296,306	932,125
Salaries and benefits	556,902	632,274	291,142	293,133
Licensing, patent legal fees and royalties	241,196	412,541	149,046	205,599
Stock based compensation	200,353	196,383	83,052	97,204
CPRIT grant claimed on eligible expenses	(951,166)	(2,918,708)	(81,890)	(1,509,772)
Other research and development expenses	114,131	18,139	60,168	8,880
	2,074,734	1,080,787	1,246,292	445,814

Research and development ("R&D") expenses of \$2,074,734 were incurred during the six months ended September 30, 2019, compared with \$1,080,787 incurred in the six months ended September 30, 2018. R&D expenses of \$1,246,292 were incurred during the three months ended September 30, 2018, compared with \$445,814 incurred

in the three months ended September 30, 2018. When accounting for amounts reimbursed by CPRIT R&D expenses of \$3,025,900 were incurred in the six months ended September 30, 2019 compared with \$3,999,495 in the six months ended September 30, 2018 and \$1,328,182 in the three months ended September 30, 2019 compared with \$1,955,586 in the three months ended September 30, 2018.

Excluding amounts received from CPRIT, R&D expenses are lower in the current year periods compared with the prior year periods and these decreases can primarily be attributed to the following factors:

- No amortization related to the research & development warrant which was fully amortized in the prior year.
- Lower clinical trial costs due to completion of enrolment in the Phase2b rGBM clinical study and the wind down of the study.
- Lower licensing, patent legal fees and royalty costs in the current year due to a pipeline prioritization completed in the prior year period.

These reductions were offset by the following increases:

- Increased regulatory costs associated with preparation for the EOP2 meeting and
- Higher discovery and pre-clinical expenses associated with the development of the MDNA19 program as we advance it towards the clinic.

#### General and Administrative Expenses

	Six months ended September 30,		Three month Septembe	
	2019	2018	2019	2018
	\$	\$	\$	\$
Depreciation expense	2,473	3,409	1,236	1,704
Stock based compensation	243,151	328,486	149,189	171,593
Facilities and operations	133,379	67,167	71,209	22,881
Legal, professional and finance	89,765	81,946	58,808	50,008
Salaries and benefits	315,939	355,237	161,556	164,344
Other expenses	444,752	283,453	200,550	102,106
CPRIT grant claimed on eligible expenses	(125,372)	(261,784)	-	(69,273)
	1,104,087	857,914	642,548	443,363

General and administrative ("G&A") expenses of \$1,104,087 were incurred during the six months ended September 30, 2019, compared with \$857,914 during the six months ended September 30, 2018. In the three months ended September 30, 2019, G&A expenses of \$642,548 were incurred compared with \$443,363 during the three months ended September 30, 2018.

The increase in G&A expenditures year over year is primarily attributed to lower amounts of expenses eligible for reimbursement from CPRIT in the current year periods as well as higher facilities and operations expenses associated with office rent and relocation costs as well as higher other expenses in the current year periods. Other expenses consist primarily of investor and public relations costs for which activity was higher in the current year periods.

Stock based compensation expense was lower in the six months ended September 30, 2019 compared with the prior year period due to the timing of grants as well as lower black scholes values of current grants.

# SUMMARY OF QUARTERLY FINANCIAL RESULTS

	Sept. 30 2019	June 30 2019	Mar. 31 2019	Dec. 31 2018	Sept. 30 2018	June 30 2018	March 31 2018	Dec. 31 2017
	\$	\$	\$	\$	\$	\$	\$	\$
Revenue	-	-	-	-	-	-	-	-
General and administration	642,548	461,539	414,154	437,218	443,363	414,551	440,454	824,007
Research and development	1,246,292	828,442	661,314	1,275,896	445,814	634,973	864,005	1,351,703
Net loss	(1,904,259)	(1,294,634)	(1,049,074)	(1,723,081)	(897,659)	(1,038,217)	(1,310,506)	(2,181,022)
Basic and diluted loss per share	(0.07)	(0.05)	(0.04)	(0.07)	(0.04)	(0.04)	(0.05)	(0.09)
Total assets	2,243,789	3,674,228	5,187,428	6,017,780	3,408,806	3.644,480	4,374,582	6,838,585
Total liabilities	2,050,249	1,897,899	2,570,871	2,512,414	2,173,528	2,000,746	2,212,757	4,534,080

R&D expenses fluctuate quarter over quarter based on the amount of expenditures eligible for CPRIT reimbursement in the period as well as the pace of the clinical trial enrollment during the period. Research and development costs in the quarter ended December 31, 2018 were higher than prior periods due to patient treatment costs and a lower CPRIT reimbursement in the quarter. During the three months ended December 31, 2017 and September 30, 2019, the CPRIT expenses eligible for offset were smaller than comparable quarters and therefore expenses were higher than comparable periods.

G&A expenses are higher in the quarter ended September 30, 2019 due to no expenditures claimed for CPRIT reimbursement as well as higher related to costs associated with investor relations activities and facilities. The increase in the quarter ended December 31, 2017 related to costs associated with stock option grants issued to general and administrative employees and directors during that quarter.

# LIQUIDITY AND CAPITAL RESOURCES

Since inception, the Company has devoted its resources to funding R&D programs, including securing intellectual property rights and licenses, conducting discovery research, manufacturing drug supplies, initiating preclinical and clinical studies, submitting regulatory dossiers and providing administrative support to R&D activities, which has resulted in an accumulated deficit of \$25,988,544 as of September 30, 2019. With current revenues only consisting of interest earned on excess cash, losses are expected to continue while the Company's R&D programs are advanced.

We currently do not earn any revenues from our drug candidates and are therefore considered to be in the development stage. As required, the Company will continue to finance its operations through the sale of equity or pursue non-dilutive funding sources available to the Company in the future. The continuation of our research and development activities and the commercialization of MDNA55 is dependent upon our ability to successfully finance and complete our research and development programs through a combination of equity financing and revenues from strategic partners. We have no current sources of revenues from strategic partners.

Management has forecasted that the Company's current level of cash along with the proceeds from the financing completed subsequent to the quarter end will be sufficient to execute its current planned expenditures for the next 12 months without further financing being obtained.

## CASH POSITION

At September 30, 2019, we had a cash balance of \$1,979,727 compared to \$2,370,976 at March 31, 2019. Subsequent to the quarter end, on October 17, 2019 we completed a public offering raising gross proceeds of \$6,900,000. We invest cash in excess of current operational requirements in highly rated and liquid instruments. Working capital at September 30, 2019 was \$287,841 (March 31, 2019: \$2,709,784). In addition, we have the proceeds raised subsequent to the quarter end as well as up to US\$1.4 million remaining available under the CPRIT grant to be used towards the development of MDNA55.

We do not expect to generate positive cash flow from operations for the foreseeable future due to additional R&D expenses, including expenses related to drug discovery, preclinical testing, clinical trials, chemistry, manufacturing and controls ("CMC") and operating expenses associated with supporting these activities. It is expected that negative cash flow from operations will continue until such time, if ever, that we receive regulatory approval to commercialize any of our products under development and/or royalty or milestone revenue from any such products should they exceed our expenses.

# CONTRACTUAL OBLIGATIONS

As of September 30, 2019, we have the following obligations to make future payments, representing contracts and other commitments that are known and committed:

	F	ayments Du	e by Period	
Contractual obligations	Less than 1 year	1-3 years	3-5 years	Total
Patent licensing costs, minimum annual royalties per license agreements	\$ 66,500	\$ 172,900	\$ 532,000	\$ 771,400
Liquidity event payment	\$ 173,034	\$ 173,034	\$ 0	\$ 346,067

The Company utilizes temporary office space with terms of less than one year.

The Company cannot reasonably estimate future royalties which may be due upon the regulatory approval of MDNA55.

# CPRIT assistance

In February 2015, the Company received notice that it had been awarded a grant by CPRIT whereby the Company is eligible to receive up to US\$14,100,000 on eligible expenditures over a three year period related to the development of the Company's phase 2b clinical program for MDNA55. On an ongoing basis, we must demonstrate that the expenditures are eligible using CPRIT's criteria, show proof that we have 50% matching funds available, that development milestones have been achieved and that best efforts have been made to establish substantial project related expenses within the state of Texas. In October 2017 the Company was granted a one-year extension to the grant allowing expenses to be claimed over a four year period ending February 28, 2019 and on February 4, 2019 the Company was granted an additional six month extension allowing expense to be claimed until August 31, 2019 and on July 25, 2019 an additional six month extension was granted to February 28, 2020.

Of the US\$14.1 million grant approved by CPRIT, Medicenna has received US\$13.0 million from CPRIT as of September 20, 2019. The Company is eligible to receive the remaining US\$1.4 million upon the achievement of certain criteria as determined by CPRIT, from time to time. There can be no assurances that the balance of such grants will be received from CPRIT.

Ongoing program funding from CPRIT is subject to a number of conditions including the satisfactory achievement of milestones that must be met to release additional CPRIT funding, proof the Company has raised 50% matching funds and that best efforts have been made to establish substantial project related expenses within the state of Texas. If the Company is found to have used any grant proceeds for purposes other than intended, is in violation of the terms of the grant, or relocates the majority of its project related operations outside of the state of Texas, then the Company may be required to repay any grant proceeds received. There can be no assurances that the

Company will continue to meet the necessary CPRIT criteria or that CPRIT will continue to advance additional funds to the Company.

# Intellectual Property

The Company has entered into various license agreements with respect to accessing intellectual property in the form of filed and issued patents. In order to maintain these agreements, the Company is obligated to pay certain costs based on timing or certain milestones within the agreements, the timing of which is uncertain. These costs include ongoing license fees, patent prosecution and maintenance costs, royalty and other milestone payments. As at September 30, 2019, the Company is obligated to pay the following:

- Patent licensing costs due within 12 months totaling \$66,500.
- Patent licensing costs, including the above, due within the next five years totaling \$705,000.
- Project milestone payments, assuming continued success in the development programs, of uncertain timing totaling US\$2,800,000 and an additional US\$2,000,000 in sales milestones.
- A liquidity payment of \$173,034 due in 2019 and \$173,034 due in 2020 to the NIH which represents the remaining payments resulting from the Company's liquidity event in March 2017.

As part of these license agreements, the Company has committed to make certain royalty payments based on net sales to the NIH and Stanford.

# **OFF-BALANCE SHEET ARRANGEMENTS**

The Company has no material undisclosed off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our results of operations, financial condition, revenues or expenses, liquidity, capital expenditures or capital resources that is material to investors.

# TRANSACTIONS WITH RELATED PARTIES

Key management personnel, which consists of the Company's officers (Dr. Fahar Merchant, President and Chief Executive Officer, Ms. Elizabeth Williams, Chief Financial Officer, and Ms. Rosemina Merchant, Chief Development Officer) and directors, received the following compensation for the following periods:

	Six months e September		Three months September	
	2019	2018	2019	2018
	\$	\$	\$	\$
Salaries and Wages	445,874	419,062	222,937	196,125
Board Fees	70,959	71,205	35,399	35,697
Stock Option Expense	300,653	435,712	163,974	202,522
Related Party Rent	-	11,951	-	5,085
	817,486	937,930	422,310	439,429

During the six months ended September 30, 2019, the Company paid \$33,886 in moving expenses and prepaid rent to the CEO and CDO of the Company. This transaction was in the normal course of business and has been measured at the exchange amount, which is the amount of consideration established and agreed to by the related parties.

As at September 30, 2019, the Company had trade and other payables in the normal course of business, owing to directors and officers of \$381,208 (2018: \$246,058) related to deferred salary, board fees and accrued vacation.

### ACCOUNTING PRONOUNCEMENTS ADOPTED IN FISCAL 2020

The Company has adopted new accounting standard IFRS 16 - Leases, effective for the Company's annual period beginning April 1, 2019. The adoption of IFRS 16 did not result in any changes to the Company's financial statements.

IFRS 16 sets out the principles for the recognition, measurement, presentation and disclosure of leases and requires lessees to account for all leases under a single on-balance sheet model, with certain exemptions. The standard includes two recognition exemptions for lessees – leases of "low-value" assets and short-term leases with a lease term of 12 months or less. At the commencement date of a lease, a lessee will recognize a liability to make lease payments and an asset representing the right to use the underlying asset during the lease term. Lessees will be required to separately recognize the interest expense on the lease liability and the depreciation expense on the right-of-use asset. Lessees are also required to remeasure the lease liability upon the occurrence of certain events such as a change in lease term. The lessee will generally recognize the amount of the remeasurement of the lease liability as an adjustment to the right-of-use asset.

# **CRITICAL ACCOUNTING POLICIES AND ESTIMATES**

The significant accounting policies of the Company are described in note 2 of the audited consolidated financial statements for the year ended March 31, 2019 and available on SEDAR (<u>www.sedar.com</u>).

Estimates and assumptions are continually evaluated and are based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances. The determination of estimates requires the exercise of judgement based on various assumptions and other factors such as historical experience and current and expected economic conditions. Actual results could differ from those estimates. Critical judgements in applying the Company's accounting policies are detailed in the audited consolidated financial statements for the year ended March 31, 2019 filed on SEDAR (www.sedar.com).

## FINANCIAL INSTRUMENTS

#### (a) Fair value

The Company's financial instruments recognized on the consolidated statements of financial position consist of cash, other receivables, accounts payable and accrued liabilities, deferred government grants and license fee payable. The fair value of these instruments, approximate their carry values due to their short-term maturity.

#### Classification of financial instruments

Financial instruments measured at fair value on the statement of financial position are summarized into the following fair value hierarchy levels:

Level 1: quoted prices (unadjusted) in active markets for identical assets or liabilities.

Level 2: inputs other than quoted prices included within Level 1 that are observable for the asset or liability

Level 3: inputs for the asset or liability that are not based on observable market data (unobservable inputs).

The Company classifies its financial assets and liabilities depending on the purpose for which the financial instruments were acquired, their characteristics, and management intent as outlined below:

Cash is measured using Level 1 inputs and changes in fair value are recognized through profit or loss, with changes in fair value being recorded in net earnings at each period end.

Government grant receivables and other receivables have been classified as loans and receivables and are measured at amortized cost less impairments.

Accounts payable and accrued liabilities have been classified as financial liabilities.

The Company has exposure to the following risks from its use of financial instruments: credit, interest rate, currency and liquidity risk. The Company reviews its risk management framework on a quarterly basis and makes adjustments as necessary.

### (b) Financial risk management

We have exposure to credit risk, liquidity risk and market risk. Our Board of Directors has the overall responsibility for the oversight of these risks and reviews our policies on an ongoing basis to ensure that these risks are appropriately managed.

#### i. Credit risk

Credit risk arises from the potential that a counterparty will fail to perform its obligations. The financial instruments that are exposed to concentrations of credit risk consist of cash and cash equivalents.

The Company attempts to mitigate the risk associated with cash and cash equivalents by dealing only with major Canadian financial institutions with good credit ratings.

#### ii. Interest rate risk

Interest rate risk is the risk that the fair values and future cash flows of the Company will fluctuate because of changes in market interest rates. The Company believes that its exposure to interest rate risk is not significant.

#### iii. Liquidity risk

Liquidity risk is the risk that the Company will not be able to meet its financial obligations as they fall due. The Company currently settles all of its financial obligations out of cash. The ability to do so relies on the Company maintaining sufficient cash in excess of anticipated needs. As at September 30, 2019, the Company's liabilities consist of trade and other payables that have contracted maturities of less than one year.

#### iv. Currency risk

Currency risk is the risk that future cash flows of a financial instrument will fluctuate because of changes in foreign exchange rates. The Company is exposed to currency risk from employee costs as well as the purchase of goods and services primarily in the United States and the cash balances held in foreign currencies. Fluctuations in the US dollar exchange rate could have a significant impact on the Company's results. Assuming all other variables remain constant, a 10% depreciation or appreciation of the Canadian dollar against the US dollar would result in an increase or decrease in loss and comprehensive loss for the three months ended September 30, 2019 of \$2,621 (March 31, 2019 - \$69,305).

#### Balances in US dollars are as follows:

	September 30, 2019	March 31, 2019
	\$	\$
Cash	1,071,161	118,440
Accounts payable and accrued liabilities	(1,051,364)	(1,430,518)
Deferred government grant receivable	-	1,831,337
	19,797	519,259

# (c) Managing Capital

The Company's objectives, when managing capital, are to safeguard cash as well as maintain financial liquidity and flexibility in order to preserve its ability to meet financial obligations and deploy capital to grow its businesses.

The Company's financial strategy is designed to maintain a flexible capital structure consistent with the objectives stated above and to respond to business growth opportunities and changes in economic conditions. In order to maintain or adjust its capital structure, the Company may issue shares or issue debt (secured, unsecured, convertible and/or other types of available debt instruments).

There were no changes to the Company's capital management policy during the year. The Company is not subject to any externally imposed capital requirements.

# USE OF PROCEEDS

The following table provides an update on the anticipated use of proceeds raised in the December 2018 equity offering along with amounts actually expended. As of September 30, 2019, the following expenditures have been incurred:

Item	Amount to Spend	Spent to Date <sup>2</sup>	Adjustments	Remaining to Spend
Patient treatment costs	\$ 1,500,000	\$ 656,966	(900,000) <sup>1</sup>	-
Clinical trial overhead costs	750,000	668,730	_	81,270
Salaries and intellectual property costs	500,000	817,569	450,000	132,431
General corporate and working capital purposes	950,000	1,173,947	450,000	226,053
Total	\$ 3,700,000	\$ 3,317,212	\$ -	\$439,754

1. Original use of proceeds assumed treatment of 52 patients in the study to reach an evaluable patient population of 46 patients. Only 46 patients were required to be treated in order to achieve 46 evaluable patients and as such a portion of the costs have been relocated to 'salaries and intellectual property costs' and 'general corporate and working capital'

2. Amounts shown are net of expenditures reimbursed from CPRIT.

# **RISKS AND UNCERTAINTIES**

Investing in our securities involves a high degree of risk. Before making an investment decision with respect to our common shares, you should carefully consider the following risk factors, in addition to the other information included or incorporated by reference into the most recently filed annual information form, as well as our historical consolidated financial statements and related notes. Management has reviewed the operations of the Company in conjunction with the Board of Directors and identified the following risk factors which are monitored on a biannual basis and reviewed with the Board of Directors. The risks set out below are not the only risks we face. If any of the following risks occurs, our business, financial condition, prospects or results of operations and cash flows would likely suffer. In that case, the trading price of our common shares could decline and you may lose all or part of the money you paid to buy our common shares.

Please refer to our MD&A and annual information form for the year ended March 31, 2019 for a complete discussion of risks and uncertainties.

- We have no sources of product revenue and will not be able to maintain operations and research and development without sufficient funding.
- We are highly dependent upon certain key personnel and their loss could adversely affect our ability to achieve our business objective.
- If we breach any of the agreements under which we license rights to product candidates or technology from third parties, we can lose license rights that are important to our business. Our current license agreements may not provide an adequate remedy for breach by the licensor.
- Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results and our product candidates may not have favourable results in later trials or in the commercial setting.
- We are subject to the restrictions and conditions of the CPRIT agreement. Failure to comply with the CPRIT agreement may adversely affect our financial condition and results of operations.
- If our competitors develop and market products that are more effective than our existing product candidates or any products that we may develop, or obtain marketing approval before we do, our products may be rendered obsolete or uncompetitive.
- We rely and will continue to rely on third parties to plan, conduct and monitor preclinical studies and clinical trials, and their failure to perform as required could cause substantial harm to our business.
- We rely on contract manufacturers over whom we have limited control. If we are subject to quality, cost or delivery issues with the preclinical and clinical grade materials supplied by contract manufacturers, business operations could suffer significant harm.
- Our future success is dependent primarily on the regulatory approval of a single product. MDNA55 is in the mid stages of clinical development and MDNA19 in pre-clinical development and, as a result, we will be unable to predict whether we will be able to profitably commercialize our product.
- We will be subject to extensive government regulation that will increase the cost and uncertainty associated with gaining final regulatory approval of its product candidates.
- Negative results from clinical trials or studies of third parties and adverse safety events involving the targets of our products may have an adverse impact on future commercialization efforts.
- If we are unable to enroll subjects in clinical trials, we will be unable to complete these trials on a timely basis.
- We face the risk of product liability claims, which could exceed our insurance coverage and produce recalls, each of which could deplete cash resources.
- We may not achieve our publicly announced milestones according to schedule, or at all.
- Changes in government regulations, although beyond our control, could have an adverse effect on our business.
- Our significant shareholders may have material influence over our governance and operations.
- Our discovery and development processes involve use of hazardous and radioactive materials which may result in potential environmental exposure.
- If we are unable to successfully develop companion diagnostics for our therapeutic product candidates, or experience significant delays in doing so, we may not achieve marketing approval or realize the full commercial potential of our therapeutic product candidates.
- Significant disruption in availability of key components for ongoing clinical studies could considerably delay completion of potential clinical trials, product testing and regulatory approval of potential product candidates.
- Our success depends upon our ability to protect our intellectual property and its proprietary technology.
- Our potential involvement in intellectual property litigation could negatively affect our business.
- Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them.
- Product liability claims are an inherent risk of our business, and if our clinical trial and product liability insurance prove inadequate, product liability claims may harm our business.
- Our common share price has been volatile in recent years, and may continue to be volatile.
- Future sales or issuances of equity securities or the conversion of securities into Common Shares could decrease the value of the Common Shares, dilute investors' voting power, and reduce earnings per share.

- We are subject to foreign exchange risk relating to the relative value of the United States dollar.
- Any failure to maintain an effective system of internal controls may result in material misstatements of our consolidated financial statements or cause us to fail to meet the reporting obligations or fail to prevent fraud; and in that case, shareholders could lose confidence in our financial reporting, which would harm the business and could negatively impact the price of the Common Shares.
- Any future profits will likely be used for the continued growth of the business and products and will not be used to pay dividends on the issued and outstanding shares.
- We may pursue other business opportunities in order to develop our business and/or products.
- Generally, a litigation risk exists for any company that may compromise our ability to conduct our business.
- Our success depends on our ability to effectively manage our growth.
- We are likely a "passive foreign investment company," which may have adverse United States federal income tax consequences for United States shareholders.
- It may be difficult for non-Canadian investors to obtain and enforce judgments against us because of our Canadian incorporation and presence.

# **OTHER MD&A REQUIREMENTS**

#### **Outstanding Share Data**

As at the date of this report, the Company has the following securities outstanding:

	Number
Common Shares	34,135,485
Warrants	7,899,408
Stock Options	3,125,000
Total	45,159,893

For a detailed summary of the outstanding securities convertible into, exercisable or exchangeable for voting or equity securities of Medicenna as at March 31, 2019, refer to Notes, 8, 9 & 10 in the audited 2019 annual financial statements of the Company.

Additional information relating to the Company, including the Company's annual information form in respect of fiscal year 2019, is available under the Company's profile on SEDAR at www.sedar.com.